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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,038	11/17/2000	Carlos Vonderwalde Freidberg	24079-1071	7272

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/11/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/716,038

Applicant(s)

FREIDBERG, CARLOS
VONDERWALDE

Examiner

Paul B. Prebilit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 29, 30, 32, 35-38 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) 10, 12-20 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 29, 30, 35-38 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 29, 2003 has been entered.

Claims 10, 12-20 and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Applicant is advised that a complete reply to this requirement must include an identification of the species that is elected and a listing of all claims readable thereon. Applicant is entitled to consideration of claims to a reasonable number of disclosed species in addition to the elected species provided all the claims to each additional species are written in dependent form or otherwise include all the limitation of an allowed generic claim as provided by 37 CFR 1.141. Applicant's reply must include an identification of such additional species along with a listing of the claims readable on each additional species.

Upon review of the amendment and parent patent US 6,468,300, the Examiner concluded that Claims 2, 5, 9, 29, 30, 36-38, and 41-46 have an effective filing date of September 17, 1998 because of the subject matter contained therein was added to the parent application 09/156,034 on the date of its filing.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-8, and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-10 of U.S. Patent No. 6,468,300 alone. The patented claims set forth greater detail with regard to the implant than the present claims such that the present claims nearly read thereon. Therefore, since the present claims can be read upon by the patented claims, it is the Examiner's position that present claims are clearly obvious in view of the patented claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, 29, 30, 35-38 and 41-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claimed range of

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"less than 0.45 mm" lacks clear antecedent basis from the specification; see page 9, line 1 to page 10, line 8. Since it is essential subject matter, it must have clear explicit support from the specification.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 9, 37, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) alone where the effective filing date of these claims is September 17, 1998. Winston discloses a thinned tissue on a stent where the tissue is thin enough to improve the viability of the graft and improve endothelial cell migration, but Winston fails to disclose the thickness of the tissue as claimed; see column 1, line 67 to column 2, line 4, column 2, lines 48-61, and column 3, lines 17-45, Figures 1-3, column 3, lines 16-59, and column 5, lines 4-20. However, the mere setting forth of a thickness is not considered sufficient to support patentability and would have been obvious to an ordinary artisan in the art. In particular, MPEP 2144.04 is incorporated herein by reference and states:

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

With regard to claim 9, Applicant is directed to Figure 3.

Claims 29, 30, 36-38 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love (97/24081) in view of Winston et al (US 6,117,166). Love meets the claim language fully except for the thinned state of the tissue as claimed; see pages 8 and 9. Winston et al, however, teaches that it was known to thin tissue for similar devices such that the claimed thickness is obvious as a way to improve the viability of the implant; see the abstract and the previously cited portions. Hence, it is the Examiner's position that it would have been obvious to use thinned tissue in the Love device for the same reasons that Winston et al uses the same.

With regard to claim 36 specifically, Love teaches that it was known to have the inner and outer layers longer than the stent but not specifically by less than 5 % as claimed. However, since there is not criticality for this feature, it is the Examiner's position that it would have been prima facie obvious to match the length of the stent and tissue cover closely in order to reduce the cost of making the device and in order to prevent loose tissue ends from causing thrombosis of the vessel.

Claims 1-4, 6-9, 11, 29, 30, 36-38, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love (WO 97/24081) in view of Love et al (US 5,163,955). Love (WO) discloses a tubular support frame made of expandable material (spring steel or Nitinol, see page 10, lines 21-27) which is wrapped with pericardial tissue or similar tissues; see page 4, lines 12-29, page 5, lines 7-33, and page 9, lines 26-29. Love (WO), however, fails to teach the thickness of the pericardial

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or other tissues used in the invention. However, Love et al (US) teaches that pericardial tissue varies in thickness from about 15 to 20 mils (i.e. 0.38 to 0.51 mm); see column 15, line 64 to column 16, line 7. Furthermore, the mere setting forth of a thickness is not considered sufficient to support patentability and would have been obvious to an ordinary artisan in the art; there is no criticality set forth or shown for the less than 0.45 mm thickness range claimed. In particular, MPEP 2144.04 is incorporated herein by reference and states:

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Hence, it is the Examiner's position that it would have been obvious to use bovine pericardial tissue of 15 mils or 0.38 mm thickness because it would keep the implant profile lower than a thicker tissue and because it would function in the same manner as that set forth by Love's broader range.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) in view of Narciso (WO 94/15583). Winston et al fails to include a therapeutic material in the graft thereof. Narciso teaches that it was known to use therapeutic materials in similar implants. Hence, it is the Examiner's position that it would have been obvious to do the same for the same reasons that Narciso does the same.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Love (WO 97/24081) and Love et al (US 5,163,955) as set forth in the previous rejection and in further view of Dereume (US 5,653,747). Love and Love et al renders the claim language obvious as set forth in the rejection of claim 1 above, but Love fails to teach the concept of having the jacket shorter than the stent or support as claimed. Dereume, however, teaches that it was known to make the graft slightly shorter than the stent or support; see the figures. Therefore, it is the Examiner's position that it would have been obvious to make the support of Love longer than the tissue graft is supports for the same reasons that Dereume does the same in the invention thereof.

Response to Arguments

Applicant's arguments filed April 29, 2003 have been fully considered but they are not persuasive.

In traversing the Winston rejections, Applicant argues that the effective filing date of the present claims is that of parent application 08/935,784 or September 23, 1997. However, since claims 2, 5, 9, 29, 30, 36-38, and 41-46 contain limitations that are not supported thereby, they have a effective filing date of September 17, 1998. In particular, claim 2 set forth vein and artery grafts, claim 5 sets forth a therapeutic or diagnostic agent releasably contained in the jacket, claim 29 sets forth that the outer surface of the stent is wrapped with the tissue and "configured to unwrap as the stent expands.", and the remaining claims have limitations not supported by the disclosure of

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08/935,784. For this reason, the Examiner believes that the effective filing date of the claims is September 17, 1998 or that of the parent application 09/156,034.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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